

# CLIAC April 2018: Topic Discussion Questions and Background Information



## Implementation of Next Generation Sequencing in Public Health and Clinical Laboratories

### **Discussion Questions for CLIAC Consideration:**

1. What major gaps and issues do laboratories experience when implementing NGS-based testing for various applications?
2. What guidance is lacking for laboratories that perform NGS testing to address critical steps in the total testing process?
3. How can CDC, CMS, and FDA assist in filling NGS-related gaps and providing guidance to laboratories?

## Clinical Laboratory Workforce

### **Discussion Questions for CLIAC Consideration:**

1. How do we best assess workforce development needs and the gaps in meeting them?
2. How can CDC, CMS, and FDA assist in filling needs in the areas of workforce development and training?

### **Background Information:**

1. Workforce Shortage CLIAC Summary  
[https://ftp.cdc.gov/pub/CLIAC\\_meeting\\_presentations/pdf/Addenda/cliac0418/9a\\_Workforce\\_Shortage\\_CLIAC\\_Summary\\_03292018.pdf](https://ftp.cdc.gov/pub/CLIAC_meeting_presentations/pdf/Addenda/cliac0418/9a_Workforce_Shortage_CLIAC_Summary_03292018.pdf)

## Laboratory Interoperability

### **Discussion Questions for CLIAC Consideration:**

1. What challenges remain for achieving semantic interoperability?
2. How can CMS, FDA, and CDC facilitate addressing those challenges?
3. How can CMS, FDA and CDC support industry in their efforts to provide standard test codes for laboratories?
4. What incentives would laboratories need to voluntarily implement the laboratory data exchange standards? (HL7, LOINC, SNOMED, UCUM, LIVD)

### **Background Information:**

1. CLIAC Recommendations Interoperability  
[https://ftp.cdc.gov/pub/CLIAC\\_meeting\\_presentations/pdf/Addenda/cliac0418/12a\\_CLIAC\\_Recommendations\\_Interoperability.pdf](https://ftp.cdc.gov/pub/CLIAC_meeting_presentations/pdf/Addenda/cliac0418/12a_CLIAC_Recommendations_Interoperability.pdf)
2. Laboratory Interoperability Discussions  
[https://ftp.cdc.gov/pub/CLIAC\\_meeting\\_presentations/pdf/Addenda/cliac0418/12b\\_Laboratory%20Interoperability%20Discussions\\_04052018.pdf](https://ftp.cdc.gov/pub/CLIAC_meeting_presentations/pdf/Addenda/cliac0418/12b_Laboratory%20Interoperability%20Discussions_04052018.pdf)
3. IICC LAW and LIVD Handout  
[https://ftp.cdc.gov/pub/CLIAC\\_meeting\\_presentations/pdf/Addenda/cliac0418/15a\\_IICC\\_LAW\\_and\\_LIVD\\_Handout.pdf](https://ftp.cdc.gov/pub/CLIAC_meeting_presentations/pdf/Addenda/cliac0418/15a_IICC_LAW_and_LIVD_Handout.pdf)
4. Interoperability LIVD Example  
[https://ftp.cdc.gov/pub/CLIAC\\_meeting\\_presentations/pdf/Addenda/cliac0418/15b\\_Heierman\\_Interoperability\\_LIVDExcelDigitalFormatExample.pdf](https://ftp.cdc.gov/pub/CLIAC_meeting_presentations/pdf/Addenda/cliac0418/15b_Heierman_Interoperability_LIVDExcelDigitalFormatExample.pdf)

## Using Clinical Laboratory Data to Improve Quality and Laboratory Medicine Practices

### **Discussion Questions for CLIAC Consideration:**

1. What areas of health care have had quality transformed by big data? What were the metrics of success and lessons learned?
2. How can clinical laboratory data be used effectively to identify quality-related issues and provide evidence to demonstrate the value of the laboratory?
3. What are the challenges in using laboratory data for these purposes?
4. How can CDC, CMS, and FDA guide and support HHS policies that encourage such use of clinical laboratory and pathology data?

### **Background Information:**

1. Sawhney S, Fraser SD. Epidemiology of AKI: Utilizing Large Databases to Determine the Burden of AKI. *Advances in Chronic Kidney Disease*. 2017;24(4):194-204. doi:10.1053/j.ackd.2017.05.001.  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5648688/>
2. Siew ED, Basu RK, Wunsch H, et al. Optimizing administrative datasets to examine acute kidney injury in the era of big data: workgroup statement from the 15<sup>th</sup> ADQI Consensus Conference. *Canadian Journal of Kidney Health and Disease*. 2016;3:12. doi:10.1186/s40697-016-0098-5.  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4768415/>
3. Sutherland S, M, Goldstein S, L, Bagshaw S, M, Leveraging Big Data and Electronic Health Records to Enhance Novel Approaches to Acute Kidney Injury Research and Care. *Blood Purif* 2017;44:68-76.  
<https://www.karger.com/Article/Pdf/458751>
4. Mehta R, Bihorac A, Selby NM, et al. Establishing a continuum of acute kidney injury – tracing AKI using data source linkage and long-term follow-up: Workgroup Statements from the 15th ADQI Consensus Conference. *Canadian Journal of Kidney Health and Disease*. 2016;3:13. doi:10.1186/s40697-016-0102-0.  
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